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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,515	06/18/2001	Klaus Schelberger	49651	1391

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EXAMINER

JIANG, SHAOJIA A

ART UNIT PAPER NUMBER

1617

DATE MAILED: 04/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/868,515

Applicant(s)

SCHELBERGER ET AL.

Examiner

Shaojia A. Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2004 and 03 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 10, 2004 has been entered.

Applicant's request for deferral/suspension of action under 37 CFR 1.103 filed on June 10, 2004 has been approved. The SUSPENSION has EXPIRED.

This Office Action is a response to Applicant's request for continued examination (RCE) filed June 10, 2004, and amendment and response to the Final Office Action (mailed March 9, 2004), filed June 10, 2004 and September 3, 2004 wherein claims 24-38 are newly submitted.

Currently, claims 12-38 are pending in this application.

Note that this application is a 371 of PCT/EP99/09803 filed December 11, 1999 which claims foreign priority to Germany 198589115 under 35 U.S.C. 119(a)-(d). The copy of certified copy of the priority has been filed with the instant Application. It is noted that Germany Application 198589115 is in Germany; no translation of said Germany application into English has been provided.

On consideration by the examiner, the specie election requirement dated October 24, 2001, is withdrawn.

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Claims 12-38 are examined on the merits herein.

The following is the new ground(s) of rejection(s).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-23 and 26-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims herein are drawn to comprise a) the compound (**Id**). The specification as originally filed fail to provide any support for the compound (**Id**) herein. Nowhere can the structure or chemical name for the compound (**Id**) be found in the specification.

The specification merely describes compounds Ia; Ib; Ic (see page 1). The specification has not taught which of compounds Ia; Ib; Ic as specific species are intended to be encompassed compound (**Id**).

More importantly, one of ordinary skill in the art would clearly recognize that the structure of compound (**Id**) differs by a significant structural feature from compounds Ia, Ib, and Id which have a morpholine ring (1,4-oxazine) or a piperidine ring, whereas compound Id contains no morpholine ring (1,4-oxazine) or piperidine ring, but has 1,3-

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dioxolane. Thus, the activity and properties of compound (Id) would be reasonably expected to separate and distinct from compounds Ia, Ib and Ic.

The court of *In re Curtis* held that “a patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when... the evidence indicates ordinary artisans could not predict the operabilityof any other species.” (see *In re Curtis* 354 F.3d 1347, 69 USPQ2d 1274, Fed. Cir. 2004). The court of *Noelle v. Lederman* also pointed out that generic claim to anti-CD40CR Mabs lacked written description support because there was no description of anti-human or other species Mabs, an no description of human CD40CR antigen. The court further pointed out that attempt to “define an unknown by its binding affinity to another unknown” failed. See 355 F.3d 1343, 69 USPQ2d 1508, Fed. Cir. 2004.

In this case, the claimed fungicidal mixture composition herein is deemed not to adequately described compound (Id). Thus, ordinary artisans could not predict the operability of compound (Id). Thus, the claimed composition is seen to clearly lack of written description.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-23 and 26-38 are rejected under 35 U.S.C. 112, first paragraph, for lack of scope of enablement for the instant combination of active agents, a), i.e.,

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compound (Id), and b), in "a synergistically effective amount", of record in the previous Office Action March 9, 2004.

Applicant's remarks filed June 10, 2004 with respect to this rejection of claims 12-23 made under 35 U.S.C. 112, first paragraph of record have been fully considered but are not deemed persuasive to remove the rejection as discussed further below.

Applicant's remarks and assertion in the declaration of Dr. Eberhard Ammermann (submitted January 29, 2002) that the data from testing of compounds la, lb and lc in combination with a single compound IIa, e.g., "Degree of action observed" compared with "Degree of action calculated", in Ammermann's declaration at page 4, demonstrates the claimed combination herein shows unexpected and synergistic activity against fungi, has been fully considered and found persuasive as to compounds la, lb and lc in combination with a single compound IIa, but not compound Id. As discussed in the previous Office Action, synergistic or superadditive effects for combinations of compounds are highly unpredictable.

As pointed out above, one of ordinary skill in the art would clearly recognize that the structure of compound (Id) differs by a significant structural feature from compounds la, lb, and lc which have a morpholine ring (1,4-oxazine) or a piperidine ring, whereas compound Id contains no morpholine ring (1,4-oxazine) or piperidine ring, but has 1,3-dioxolane. Thus, the activity and properties of compound (Id) would be reasonably expected to separate and distinct from compounds la, lb and lc.

Thus, the evidence in the examples is also not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the ingredients in the claimed composition.

Therefore, the declaration of Dr. Eberhard Ammermann (submitted January 29, 2002) is not seen to be effective and sufficient to demonstrate any synergistic effects produced by any combinations encompassed herein.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

The evidence in the declaration and specification is not seen to show clear and convincing synergy for any combination of agents within the claims. Therefore, in view of the unpredictability of such synergistic effects of the claimed combination discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test all compounds encompassed in the instant claims and their combinations, with no assurance of success.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwalge et al. (WO 97/06681, of record) and Kasahara et al. (WO 96/19442, of record) of record in the previous Office Action March 9, 2004.

Schwalge et al. (WO 97/06681 equivalent to US 5,972,941) discloses that the particular morpholine, IIa therein, (the elected species, Ia, herein), alone or in combination with the oxime compound of formula I therein in synergistically active amounts is useful in a fungicidal composition and methods for controlling harmful fungi. See US 5,972,941: abstract, col.1 lines 10-55, and the testing at col.5-6. Schwalge et al. also discloses that the mixture therein maybe in two parts wherein one part comprises Compound I therein in a solid or liquid carrier, and the other part comprises the instant particular morpholine a solid or liquid carrier; compound I therein and the instant particular morpholine are applied simultaneously together or separately or successively (see col.2 lines 7-8, col. 3 line 33 to col.4 line 36).

Kasahara et al. (WO 96/19442, equivalent to US 5,847,005) discloses that the particular oxime derivatives such as the elected species, II 79 herein in an effective amount (see Compound 376 in US 5,847,005, col. 21-22), is useful in a fungicidal composition for controlling plant diseases caused by fungi. See WO 96/19442: abstract, and equivalent to US 5,847,005: abstract, col.1 lines 9-36, and col.21-22 and testing in col. 53.

Schwalge et al. and Kasahara et al. do not expressly disclose the employment of the particular oxime derivative, II 79 herein in combination with the particular

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morpholine, Ia herein, in a fungicidal composition and a method for controlling harmful fungi.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular morpholine, Ia herein, in combination with the particular oxime derivative, II 79 herein, in a fungicidal composition and a method for controlling harmful fungi.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the particular morpholine, Ia herein, in combination with the particular oxime derivative, II 79 herein, in a fungicidal composition and a method for controlling fungi, because the particular morpholine, Ia herein, alone or in combination with an oxime compound in effective amounts is known to be useful in a fungicidal composition and a method for controlling fungi based on the prior art. Moreover, the particular oxime derivative, II 79 herein, in an effective amount is known to be useful in a fungicidal composition for controlling plant diseases caused by fungi. Therefore, one of ordinary skill in the art would have reasonably expected that combining Ia herein and II 79 herein known useful for the same purpose in a fungicidal composition would improve the fungicidal effect for controlling fungi in plants.

Since all active composition components herein are known to be useful in a fungicidal composition, it is considered prima facie obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Additionally, the teachings of Schwalge regarding the combination of the particular morpholine herein and the oxime compound therein known to be useful in a fungicidal composition exhibiting synergistic effects against the fungi further provides the motivation to make the present invention.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Applicant's remarks filed on September 3, 2004 with respect to this rejection made under 35 U.S.C. 103(a) as being unpatentable over Schwalge et al. and Kasahara et al. have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art for the following reasons.

Applicant's data shown in Ammermann's declaration and the specification herein have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention over the prior art but are not deemed persuasive, as discussed above regarding the rejection made under 35 U.S.C. 112, first paragraph, for lack scope of enablement. Thus, the evidence in the examples is also not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the active compounds in the claimed composition. See MPEP § 716.02(d). Therefore, the evidence presented in specification herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.

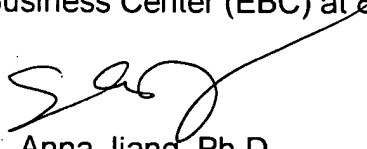
For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



S. Anna Jiang, Ph.D.
Primary Examiner
Art Unit 1617
March 18, 2005